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| 10/821,604 | 04/08/2004 | Michel Gilbert | 019633-000129US | 1518 |

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

| EXAMINER | |
|---|---|
| SWOPE, SHERIDAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/821,604 | GILBERT ET AL. | |
| | Examiner | Art Unit | |
| | Sheridan L. Swope | 1652 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *43 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's Request for Continuing Examination of October 31, 2007, in response to the Final Rejection of this case mailed October 18, 2007, is acknowledged. It is acknowledged that Applicants have amended Claims 43 and 46. Claims 43 and 46 are pending and are hereby reconsidered.

It is noted that Applicants have changed the recited invention to a polypeptide having β1,4-N-acetylgalactosaminyl (β1,4-N-GalNAc) transferase activity. In the interest of public service and compact prosecution, said new invention will be herein examined. However, any rejections based on Applicants amendment will not be considered new grounds for rejection.

### *Priority*

The priority date granted for the instant invention is April 8, 2004, the filing date of the instant Application, which disclosed the elected invention.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

### *Double Patenting*

> The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 43 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-7 of US Patent 6,723,545. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 43 and 46 herein and Claims 1-7 of 6,723,545 are both directed to an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 17. It is noted that both applications disclose that the *C. jejuni* strain OH4384 LOS locus can be amplified using the primers set forth by SEQ ID NO: 40 and 41 (Table 2) and that said locus encodes the polypeptideof SEQ ID NO: 17, which is disclosed as having β1,4-N-GalNAc activity (Table 3; sequence listing). The claims differ in that Claims 1-7 of 6,723,545 also recite β1,4-N-GalNAc polypeptides having at least 80% identity to SEQ ID NO: 17, while Claims 43 and 46 herein recite β1,4-N-GalNAc polypeptides encoded by a *Campylobactor* nucleic acid molecule that can be amplified using the primers of SEQ ID NO: 40 and 41. The portion of the specification in 6,723,545 that supports the recited polypeptides includes embodiments that would anticipate Claims 43 and 46 herein, e.g., an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 17, which are also the polypeptides specifically recited in Claims 1-7 of 6,723,545. Claims 43 and 46 herein cannot be considered patentably distinct over Claims 1-7 of 6,723,545 when there are specifically recited

embodiments (an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 17) that would anticipate Claims 43 and 46 herein. Alternatively, Claims 43 and 46 herein cannot be considered patentably distinct over Claims 1-7 of 6,723,545 when there are specifically disclosed embodiments in 6,723,545 that supports Claims 1-7 of that patent and falls within the scope of Claims 43 and 46 herein, because it would have been obvious to a skilled artisan to modify the methods of Claims 1-7 of 6,723,545 by selecting a specifically disclosed embodiment that supports those claims, i.e., an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 17, as disclosed in 6,723,545. One having ordinary skill in the art would have been motivated to do this, because such an embodiment is disclosed as being a preferred embodiment within Claims 1-7 of the prior patent.

Claims 43 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-6 of US Patent 7,238,509. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 43 and 46 herein and Claims 1-6 of 7,238,509 are both directed to an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 21. It is noted that both applications disclose that the *C. jejuni* strain OH4384 LOS locus can be amplified using the primers set forth by SEQ ID NO: 40 and 41 (Table 2) and that said locus encodes the polypeptide of SEQ ID NO: 21, which is disclosed as having β1,4-N-GalNAc activity (Table 3; sequence listing). The claims differ in that Claims 1-6 of 7,238,509 also recite β1,4-N-GalNAc polypeptides having at least 95% identity to SEQ ID NO: 21, while Claims 43 and 46 herein recite β1,4-N-GalNAc polypeptides encoded by a *Campylobactor* nucleic acid molecule that can be amplified using the primers of SEQ ID NO: 40 and 41. The portion of the specification in 7,238,509 that supports the recited

polypeptides includes embodiments that would anticipate Claims 43 and 46 herein, e.g., an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 21, which are also the polypeptides specifically recited in Claims 1-6 of 7,238,509. Claims 43 and 46 herein cannot be considered patentably distinct over Claims 1-6 of 7,238,509 when there are specifically recited embodiments (an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 21) that would anticipate Claims 43 and 46 herein. Alternatively, Claims 43 and 46 herein cannot be considered patentably distinct over Claims 1-6 of 7,238,509 when there are specifically disclosed embodiments in 7,238,509 that supports Claims 1-6 of that patent and falls within the scope of Claims 43 and 46 herein, because it would have been obvious to a skilled artisan to modify the methods of Claims 1-6 of 7,238,509 by selecting a specifically disclosed embodiment that supports those claims, i.e., an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 21, as disclosed in 7,238,509. One having ordinary skill in the art would have been motivated to do this, because such an embodiment is disclosed as being a preferred embodiment within Claims 1-6 of the prior patent.

Claims 43 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-6 of US Patent 7,169,593. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 43 and 46 herein and Claims 1-6 of 7,169,593 are both directed to an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 23. It is noted that both applications disclose that the *C. jejuni* strain OH4384 LOS locus can be amplified using the primers set forth by SEQ ID NO: 40 and 41 (Table 2) and that said locus encodes the polypeptide of SEQ ID NO: 23, which is disclosed as having β1,4-N-GalNAc activity (Table 3; sequence listing). The claims differ in

that Claims 1-6 of 7,169,593 also recite β1,4-N-GalNAc polypeptides having at least 95% identity to SEQ ID NO: 23, while Claims 43 and 46 herein recite β1,4-N-GalNAc polypeptides encoded by a *Campylobactor* nucleic acid molecule that can be amplified using the primers of SEQ ID NO: 40 and 41. The portion of the specification in 7,169,593 that supports the recited polypeptides includes embodiments that would anticipate Claims 43 and 46 herein, e.g., an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 23, which are also the polypeptides specifically recited in Claims 1-6 of 7,169,593. Claims 43 and 46 herein cannot be considered patentably distinct over Claims 1-6 of 7,169,593 when there are specifically recited embodiments (an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 23) that would anticipate Claims 43 and 46 herein. Alternatively, Claims 43 and 46 herein cannot be considered patentably distinct over Claims 1-6 of 7,169,593 when there are specifically disclosed embodiments in 7,169,593 that supports Claims 1-6 of that patent and falls within the scope of Claims 43 and 46 herein, because it would have been obvious to a skilled artisan to modify the methods of Claims 1-6 of 7,169,593 by selecting a specifically disclosed embodiment that supports those claims, i.e., an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 23, as disclosed in 7,169,593. One having ordinary skill in the art would have been motivated to do this, because such an embodiment is disclosed as being a preferred embodiment within Claims 1-6 of the prior patent.

Claims 43 and 46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 43 and 46-52 of Application 10/830,825. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 43 and 46 herein and Claims 43 and 46-52 of

10/830,825 are both directed to an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 19 or 25. It is noted that both applications disclose that the *C. jejuni* strain OH4384 LOS locus can be amplified using the primers set forth by SEQ ID NO: 40 and 41 (Table 2) and that said locus encodes the polypeptides of SEQ ID NO: 19 and 25, are disclosed as having β1,4-N-GalNAc activity (Table 3; sequence listing). The claims differ in that Claims 43 and 46-52 of 10/830,825 also recite β1,4-N-GalNAc polypeptides having at least 95% identity to SEQ ID NO: 19, while Claims 43 and 46 herein recite β1,4-N-GalNAc polypeptides encoded by a *Campylobactor* nucleic acid molecule that can be amplified using the primers of SEQ ID NO: 40 and 41. The portion of the specification in 10/830,825 that supports the recited polypeptides includes embodiments that would anticipate Claims 43 and 46 herein, e.g., an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 19 or 25, which are also the polypeptides specifically recited in Claims 43 and 46-52 of 10/830,825. Claims 43 and 46 herein cannot be considered patentably distinct over Claims 43 and 46-52 of 10/830,825 when there are specifically recited embodiments (an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 19 or 25) that would anticipate Claims 43 and 46 herein. Alternatively, Claims 43 and 46 herein cannot be considered patentably distinct over Claims 43 and 46-52 of 10/830,825 when there are specifically disclosed embodiments in 10/830,825 that supports Claims 43 and 46-52 of that application and falls within the scope of Claims 43 and 46 herein, because it would have been obvious to a skilled artisan to modify the methods of Claims 43 and 46-52 of 10/830,825 by selecting a specifically disclosed embodiment that supports those claims, i.e., an isolated or recombinantly produced polypeptide comprising SEQ ID NO: 19 or 25, as disclosed in 10/830,825. One having ordinary skill in the art would have been motivated to do this,

because such an embodiment is disclosed as being a preferred embodiment within Claims 43 and 46-52 of the other application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Enablement**

Claims 43 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a β1,4-N-GalNAc transferase polypeptide encoded by a nucleic acid molecule that can be amplified by PCR using Campylobacter jejuni OH4384 genomic DNA and primers consisting of SEQ ID NO: 40 and SEQ ID NO: 41, does not reasonably provide enablement for any β1,4-N-GalNAc transferase polypeptide encoded by any nucleic acid molecule that can be amplified by PCR using any Campylobacter genomic DNA and any primer comprising SEQ ID NO: 40 and any primer comprising SEQ ID NO: 41. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to:

(1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 43 and 46 are so broad as to encompass any β1,4-N-GalNAc transferase polypeptide encoded by any nucleic acid molecule that can be amplified by PCR using any Campylobacter genomic DNA and any primer comprising SEQ ID NO: 40 and any primer comprising SEQ ID NO: 41. The scope of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired β1,4-N-GalNAc transferase activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the β1,4-N-GalNAc transferases set forth by SEQ ID NO: 17, 19, 21, 23, and 25.

While methods for designing primers, amplifying DNA, expressing the encoded protein, and testing for β1,4-N-GalNAc transferase activity are known, it is not routine in the art to screen all polypeptides, encoded by any nucleic acid molecule that can be amplified by PCR using any Campylobacter genomic DNA and any primer comprising SEQ ID NO: 40 and any primer

comprising SEQ ID NO: 41, for β1,4-N-GalNAc transferase activity. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galye et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 43 and 46, which encompasses all β1,4-N-GalNAc transferase polypeptide encoded by any nucleic acid molecule that can be amplified by PCR using any Campylobacter genomic DNA and any primer comprising SEQ ID NO: 40 and any primer comprising SEQ ID NO: 41. The specification does not support the broad scope of Claims 43 and 46 because the specification does not establish: (A) the structure of all primers comprising SEQ ID NO: 40 or 41 that can be used to amplify polynucleotides encoding polypeptides having the desired activity; (B) how the primers of SEQ ID NO: 40 and 41 can be modified without affecting the desired ability to amplify polynucleotides encoding polypeptides with β1,4-N-GalNAc transferase activity; (C) the general tolerance of the desired amplification activity to modification of SEQ ID NO: 40 and 41 and extent of such tolerance; (D) a rational and predictable scheme for choosing which primers can be used with which Campylobacter DNA with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope

of the claims broadly including any number of polypeptides encoded by any number of nucleic acid molecules that can be amplified by PCR using any Campylobacter genomic DNA and any number of primers comprising SEQ ID NO: 40 and any number of primers comprising SEQ ID NO: 41, wherein the polypeptide has β1,4-N-GalNAc transferase activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

**Written Description**

Claims 43 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of polypeptides encoded by any number of nucleic acid molecules that can be amplified by PCR using any Campylobacter genomic DNA and any number of primers comprising SEQ ID NO: 40 and any number of primers comprising SEQ ID NO: 41, wherein the polypeptide has β1,4-N-GalNAc transferase activity. The specification teaches the structure of only five representative species of such polypeptides, wherein all said polypeptide are amplified from Campylobacter jejuni OH4384 using primers consisting of SEQ ID NO: 40 and 41. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being a

Campylobacter β1,4-N-GalNAc transferase. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

***Allowable Subject Matter***

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to reject amended claims or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

**Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1652